

REMARKS

Upon entry of the foregoing amendments, claims 27, 29, 30, 34-36 and 56-57 are pending in the application. New claims 56 and 57 have been added. Basis for the new claims can be found throughout the specification and claims, for example at paragraphs 8-12 and 24 of the published application, as well as each of the Examples. Therefore, the new claims do not introduce any new matter within the meaning of U.S.C. §132. Therefore, entry of the amendments is respectfully requested.

REJECTIONS UNDER 35 U.S.C. §103(a)

I. Erneta et al. in view of Oberhoffner et al.

Claims 27, 29-30, and 36 are rejected as being unpatentable over Erneta et al. (US 5,854,383) in view of Oberhoffner et al. (US 6,048,947).

Applicants respectfully traverse this rejection. The Examiner has failed to establish a prima facie case of obviousness based on Erneta and Oberhoffer, because the references, when considered alone and in combination, do not teach each and every limitation of the present claims. Further, the Examiner has relied on a retrospective point of view and hindsight, both of which are only possible and coherent in view of the disclosure of the instant application. Finally, one of skill in the art, when taking the teachings of Erneta and Oberhoffer, either alone or in combination, would not have had any motivation to modify the teachings thereof to arrive at the instant subject matter, and more specifically, one of skill in the art would not have had any reasonable expectation of success in said hypothetical modification, because the teachings of references are not directed and give no guidance with respect to the features presently claimed.

As previously stated, the invention according to the instant claims is drawn to a suture material for surgery comprising one or more filaments have a coating thereon, wherein the coating comprises a bioresorbable polymer, which is formed from a random terpolymer having a completely amorphous structure consisting essentially of

glycolide, ϵ -caprolactone and trimethylene carbonate, wherein the terpolymer contained glycolide in a portion of 10 to 20 wt. %, with the remainder being ϵ -caprolactone and trimethylene carbonate in a weight ratio between 30:70 and 70:30, and wherein the terpolymer has a glass transition temperature in the range of -40 to 0°C . Specifically, the terpolymer according to the present application is formed by the simultaneous reaction of the monomers of glycolide, ϵ -caprolactone and trimethylene carbonate as a random polymer. New claims have been added to further show that the coating is 0.2 to 50% of the total weight of the suture material, as well as additional features discussed during the interview with the Examiner in January 2005.

The random polymers of the instant subject matter are prepared by simultaneous reaction of all of the monomer components involved. As such, this single-step reaction resulting in the random polymer product produces a final product wherein the comonomers appear in irregular, unspecified sequences along the polymer chain.

In contrast, both Erneta and Oberhoffner disclose segmented triblockterpolymers of the A-B-A type, which are obtained in a step-wise reaction of components and result in sections or blocks of prepolymer moieties.

Erneta discloses segmented polymers, specifically blockpolymers, which are prepared by a multi-step reaction to the first TMC, caprolactone, and glycolide to obtain a first terpolymer (B), and a subsequent reaction of the thus obtained prepolymer with glycolide. See, col. 2, lines 4-

14. Subsequently, homopolymer sequences (A) are formed on both ends of the terpolymer (B) to arrive at the triblock polymer ABA. As such, the polymers of Erneta are sequential blockcopolymers, rather than the random polymers of the instant subject matter. Erneta is silent with respect to properties of the prepolymers like glass transition temperature, modulus and the like.

Further, the substantially different configuration of the blockcopolymers taught by Erneta results in a polymer having entirely different properties than the instant subject matter. For example, in contrast to the completely amorphous structure of the polymer of the instant application, Erneta teaches a polymer having at least some degree of crystallinity due to the homopolymer sequences (A). See, col. 2, lines 29-35. The partial crystallinity results in a significantly increased modulus and thus increased rigidity and stiffness of the product at room temperature. Consequently, these mechanical properties have a substantial effect on the handling characteristics of the materials taught by Erneta, such as knotting.

Additionally, the segmented polymer of Erneta is characterized by a molar mass of 20,000 to 300,000 g/mol. See, col. 4, lines 1-6. Both inherent viscosity and solubility of a polymer are controlled by molecular weight. Erneta teaches that a coating polymer according to its teachings is characterized by a low molar mass and an inherent viscosity of 0.15 to 0.75 dL/g, as measured in a solution of 0.1 g/dL HFIP at 25°C. See, col. 5, lines 38-42. However, as there are different concentrations of

polymer taught in Erneta, when compared to the instant subject matter, Applicants have undertaken additional experiments to allow for a comparison of the viscosities. Thus, it has been determined that with a concentration of $c = 0.5$ g/dL to those determined with $c = 0.1$ g/dL, the 0.5 g/dL results must be multiplied by a factor of 1.3. Accordingly, a viscosity of 0.7 dL/g measured at $c = 0.5$ g/dL results in a comparable value of 0.91 dL/g, and as such, the viscosity of the instant subject matter is clearly higher than the 0.75 dL/g of the low molecular weight example taught in Erneta. Thus, Erneta does not teach the viscosity according to the instant invention.

With respect to higher viscosities, the resultant product will be subject to increased wear resistance. Furthermore, there is no need for restriction to low molecular weight of the terpolymer according to the instant subject matter as taught by Erneta, because the random polymer will, even at a high molecular mass, be soluble in common solvents.

Oberhoffer does not remedy the deficiencies in Erneta, and likewise does not render the instant subject matter obvious to one of skill in the art. Throughout the specification of Oberhoffer, there is no indication whatsoever that any prepolymer or fractional portion of a polymer would have a stand-alone utility. The triblock polymers taught by Oberhoffer is not obtained by "advancing", "supplementing" or "upgrading" any per se utile segment portion of the polymer to yield the triblock terpolymer. Furthermore, one of skill in the art is not

given any inspiration to split up the Oberhoffer polymer to employ part of the polymer chain in a different application.

The instant subject matter is a combination of both filaments and coating to yield a suture material. To point up the differences between the present invention and the art of record, Examiner's attention is drawn to claims 56-58, which have been added to the instant application.

Examiner has failed to show how the assumed knowledge of one of skill in the art would have been obvious at the time of the invention. As stated above, Oberhoffer does not provide any reason or motivation to use the segment of the triblock polymer alone.

Based upon the foregoing, each and every limitation of the claims of the present application is not taught. Neither reference shows a completely amorphous random terpolymer for use as a suture coating material. Furthermore, the references alone and in combination provide no motivation or reasonable expectation of success that modification of the teaching contained therein would lead one of skill in the art to arrive at the coatings as presently claimed.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

II. Erneta et al. in view of Oberhoffner et al.
further in view of Bezwada

Claims 34-36 have been rejected as unpatentable over Erneta, in view of Oberhoffner and further in view of Bezwada.

Applicants traverse this rejection, and submit the foregoing with respect to claims 27, 29-30 and 36 and Erneta and Oberhoffner for the instant rejection.

The Bezwada reference does not remedy the deficiencies of Erneta and Oberhoffner. Bezwada teaches terpolymers composed of castor oil, but does not suggest any other monomers, such as trimethylene carbonate. The teachings and suggestions of Bezwada, when combined with Erneta and Oberhoffner do not lead to the instantly claimed subject matter and specifically do not teach a random, completely amorphous terpolymer comprise only of glycolide, ϵ -caprolactone and trimethylene carbonate. Specifically, there is nothing in the reference to lead one of skill in the art to modify the teachings of Erneta and Oberhoffner to arrive at the instant subject matter.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections. Favorable action with an early allowance of all claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

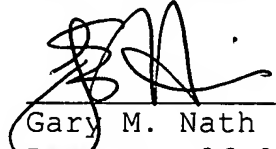
Respectfully submitted,

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